



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Scientific Opinion on the substantiation of a health claim related to a combination of Bifidobacterium longum LA 101, Lactobacillus helveticus LA 102, Lactococcus lactis LA 103 and Streptococcus thermophilus LA 104 and improves stool frequency pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stool frequency pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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ABSTRACT

Following an application from PiLeJe submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stools frequency. The food that is the subject of the health claim is a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104. The information provided was insufficient to establish that the strain *L. lactis* LA 103 was sufficiently characterised. The Panel considers that if in a combination of several microorganisms and/or ingredients one microorganism or ingredient used in the combination is not sufficiently characterised, then the combination is considered to be not sufficiently characterised. A combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103, and *S. thermophilus* LA 104 is not sufficiently characterised. The Panel concludes that a cause and effect relationship cannot be established between the consumption of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 and improves stool frequency.

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KEY WORDS

Bifidobacterium longum LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103, *Streptococcus thermophilus* LA 104, stool frequency, health claims.

¹ On request from the Competent Authority of France following an application by PiLeJe, Question No EFSA-Q-2012-00589, adopted on 24 January 2013.

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SUMMARY

Following an application from PiLeJe, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stool frequency.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and health claim including a request for the protection of proprietary data.

The food that is the subject of the health claim is a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104.

Upon a request by EFSA during the clock-stop procedure to provide information on the characterisation of the strain *L. lactis* LA 103 (molecular typing), the applicant did not provide additional information. The Panel notes that the information provided was insufficient to establish that *L. lactis* LA 103 was sufficiently characterised. The Panel considers that if in a combination of several microorganisms and/or ingredients one microorganism or ingredient used in the combination is not sufficiently characterised, then the combination is considered to be not sufficiently characterised.

The Panel considers that the food, a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104, which is the subject of the claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 and improves stool frequency.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 15/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.
- On 14/06/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 10/07/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/07/2012.
- On 25/10/2012, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 31/10/2012 and restarted on 14/11/2012, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 14/11/2012, EFSA received the requested information (which was made available to EFSA in electronic format on 13/11/2012).
- During its meeting on 24/01/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stools frequency.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stools frequency.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactobacillus lactis* LA 103 and *Streptococcus thermophilus* LA 104, a positive assessment of its safety, nor a

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

decision on whether a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: PiLeJe, 37 Quai de Grenelle, 75738 Paris Cedex 15, France.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006 (Drouault-Holowacz et al., 2008 study).

Food/constituent as stated by the applicant

According to the applicant, the food supplement (Lactibiane Référence®; 2.5 g per sachet) for which a health claim is made is a combination of four probiotics (*Bifidobacterium longum* LA 101 [29%], *Lactobacillus helveticus* LA 102 [29%], *Lactococcus lactis* LA 103 [29%] and *Streptococcus thermophilus* LA 104 [13%]) with other excipients: 1.96 g potato starch (Perfectamyl D6), 0.25 g dextrose (ROFEROSE® ST), 0.03 g maltodextrin (GLUCIDEX®), 0.125 g chicory fructo-oligosaccharides (Beneo®P95) and 0.025 g cellulose (Avicell® PH).

In further communications with EFSA, the applicant indicated that the food that was the subject of the health claim was the combination of the four bacterial strains, and not the product Lactibiane Référence® as stated initially.

Health relationship as claimed by the applicant

According to the applicant, the product being the subject of the claim improves intestinal transit.

In further communications with EFSA, the applicant indicated that the claimed effect should be changed into “improves stool frequency”, and not “improves intestinal transit” as stated initially.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wordings for the health claim: “regulates your (intestinal) transit”, “improves intestinal peristaltism”, “helps to increase stools frequency”.

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of one sachet (2.5 g) per day for 28 days. Each sachet has to be taken once daily in the fasting state, at least three hours after a meal and 15 minutes before the next meal. The powder has to be dissolved in water ten minutes before its ingestion. The target population is people characterised by a digestive discomfort such as bloating and flatulence and change in stool frequency.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim was initially identified as the product Lactibiane Référence® (2.5 g per sachet), which is a combination of four bacterial strains (*Bifidobacterium longum* LA 101 [29%], *Lactobacillus helveticus* LA 102 [29%], *Lactococcus lactis* LA 103 [29%] and *Streptococcus thermophilus* LA 104 [13%]) with other food ingredients or excipients: 1.96 g potato starch (Perfectamyl D6), 0.25 g dextrose (ROFEROSE® ST), 0.03 g maltodextrin (GLUCIDEX®), 0.125 g chicory fructo-oligosaccharides (Beneo®P95) and 0.025 g cellulose (Avicell® PH). Upon request by EFSA, the applicant indicated the content of the bacterial strains in the product in colony forming units (CFU): CFU/per sachet (2.9×10^9 CFU *B. longum* LA 101; 2.9×10^9 CFU *L. helveticus* LA 102; 2.9×10^9 CFU *L. lactis* LA 103; 1.3×10^9 CFU *S. thermophilus* LA 104). In further communications with EFSA, the applicant also indicated that the food that was the subject of the health claim was the combination of the four bacterial strains, and not the product Lactibiane Référence® as stated initially. Data related to microbiological safety and stability of the strains were provided.

The strain *B. longum* LA 101 (also named R0175) was deposited in the “Collection Nationale de Cultures de Microorganismes” (CNCM) under the deposit number I-3470. The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty. Data on phenotypic (morphology, fermentation pattern, biochemical tests) and genotypic characterisation of the strain, including species-specific PCR and 16S rDNA and *tuf* gene sequence analyses for species identification, and PFGE for strain typing, were provided. The Panel considers that the strain *B. longum* LA 101 is sufficiently characterised.

The strain *L. helveticus* LA 102 (also named R0052) was deposited in the “Collection Nationale de Cultures de Microorganismes” (CNCM) under the deposit number I-1722. Data on phenotypic (morphology, fermentation pattern, enzymatic activities, 2D-protein analysis) and genotypic characterisation of the strain, including 16S rDNA and 16S-23S rDNA intergenic region sequence analyses, DNA-DNA hybridization and ARDRA for species identification, and PFGE for strain typing, were provided. According to the applicant, this strain was initially identified as *L. acidophilus*, but more recently re-classified as *L. helveticus*. The Panel considers that the strain *L. helveticus* LA 102 is sufficiently characterised.

The strain *L. lactis* LA 103 (also named R1058) was deposited in the “Collection Nationale de Cultures de Microorganismes” (CNCM) under the deposit number MA 67/4J. Data on phenotypic (morphology, fermentation pattern, biochemical tests) and genotypic characterisation of the strain were provided only at species level (16S rDNA sequence analysis). The Panel notes that information on the strain characterisation (molecular typing) was not provided. Upon a request by EFSA, the applicant did not provide additional information. The Panel considers that the strain *L. lactis* LA 103 is not sufficiently characterised.

The strain *S. thermophilus* LA 104 (also named R1018) was characterised phenotypically (morphology, fermentation pattern, biochemical tests) and genotypically, including 16S rDNA sequence analysis for species identification and PFGE for strain typing. Upon a request by EFSA, the applicant indicated that this strain was deposited in the “Collection Nationale de Cultures de Microorganismes” (CNCM) with the number CNCM-I4691. The Panel considers that the strain *S. thermophilus* LA 104 is sufficiently characterised.

The Panel notes that in the case of a combination of several bacteria the combination is considered to be not sufficiently characterised if one microorganism used in the combination is not sufficiently characterised.

The Panel considers that the food, a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104, which is the subject of the health claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stool frequency.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food product, a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104, which is the subject of the health claim, is not sufficiently characterised.
- A cause and effect relationship cannot be established between the consumption of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stool frequency.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improves stool frequency pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0352_FR). July 2012. Submitted by PiLeJe.

REFERENCES

Drouault-Holowacz S, Bieuvelet S, Burckel A, Cazaubiel M, Dray X, Marteau P, 2008. A double blind randomized controlled trial of a probiotic combination in 100 patients with irritable bowel syndrome. *Gastroentérologie Clinique et Biologique*, 32, 147-152.

GLOSSARY AND ABBREVIATIONS

ARDRA	amplified rDNA restriction analysis
CFU	colony forming units
CNCM	Collection Nationale de Cultures de Microorganismes
DNA	deoxyribonucleic acid
PCR	polymerase chain reaction
PFGE	pulse field gel electrophoresis